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10/568,649	02/16/2006	Giorgio Terenghi	TEPH109	4566

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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,649	TERENGHI ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-14* is/are pending in the application.

4a) Of the above claim(s) *7-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 3-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed on May 4, 2007 is acknowledged. Claim 2 is cancelled. Claims 1, 3-14 are pending in this application. Claims 7-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

2. Claims 1, 3-6 are under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on May 4, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

5. The rejection of claims 1, 3-6 under 35 U.S.C. 112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is withdrawn in response to Applicants' arguments.

Claim Rejections/Objections Maintained

Obviousness-Type Non-Statutory Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-34 of U.S. Patent No. 6610764, claims 1-4, 6-28 of US 6838493, claims 1-3, 5-20 of US 6548569, claims 1-4, 6-30 of US 6867247, claims 30, 35-61 of US 7179883, for the reasons made of record in Paper No.20070202, and as set forth below.

7. Claims 1, 3-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18, 21-25 of copending Application No. 10/835926 (US2004/0234576), which has a common assignee, and claims 1-8 of copending Application No. 11/193580 (US2006/0058470), which has a common assignee, for the reasons made of record in Paper no. 20070202, and as follows.

Applicants argue that the prior art does not disclose the claimed nerve conduit made of 4-hydroxybutyrate polymers in a form of a tube or sheet and having pores

between 5-500um in diameter (p. 5 of the response). Applicants' arguments have been fully considered but they are not persuasive.

In contrast to Applicant assertion, the issued patents and copending application teach a biocompatible polyhydroxyalkanoate composition, or a device or a polymeric filament or fiber for a medical device comprising 4-hydroxybutyrate polymers for different medical uses including nerve regeneration. Although the claims do not recite the shape and size, the specification teaches a biodegradable device "comprising" a polyhydroxyalkanoate polymer comprising 4-hydroxybutyrate in a form of porous conduit such as the NEUROTUBE™ products described by the references, which is reasonably in the form of a tube with a pore size of 5-500μm in diameter. Note that the intended use for nerve regeneration is not given patentable weight since the composition of the issued patents and copending applications is the same as in the instant application and can perform the same function as in the instant claimed product. Thus, the issue patents and copending applications anticipate the claimed invention. Thus, the issue patents and the claimed device of the instant claim an invention substantially overlapping in scope.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6 stand rejected under 35 U.S.C. 102(a) & 102(e) as being anticipated by US 6548569 (issued on Apr 15, 2003, priority date Mar 25, 1999), for the reasons made of record in Paper No.20070202, and as set forth below.

9. Claims 1, 3-6 stand rejected under 35 U.S.C. 102 (b) as being anticipated by each of the following individual references: US2002/0156150 (US Application No. 10/082954, published Oct 24, 2002) and US2002/017358 (US Application No. 10/136499, published Nov 21, 2002), for the reasons made of record in Paper No.20070202, and as set forth below.

10. Claims 1, 3-6 stand rejected under 35 U.S.C. 102(e) as being anticipated by each of the following individual references: U.S. Patent No. 6610764 (issued on Aug 26, 2003, priority date Nov 17, 1997), US 6838493 (issued on Jan 4, 2005, priority date Mar 25, 1999), US 6867247 (issued Mar 15, 2005, priority date Mar 25,1999), US 7179883 (issued on May 19, 2005, priority date Mar 25, 1999), for the reasons made of record in Paper No.20070202, and as set forth below.

Applicants argue that the prior art does not disclose the claimed nerve conduit made of 4-hydroxybutyrate polymers in a form of a tube or sheet and having pores

between 5-500um in diameter (p. 5 of the response). Applicants' arguments have been fully considered but they are not persuasive.

In contrast to Applicant assertion (p.5 of the response), US 6548569 does teach devices of tissue regeneration or nerve guidance/regeneration formed of biocompatible polyhydroxyalkanoates "comprising" poly-4-hydroxybutyrate (i.e. as it relates to claims 1, 3-5; see col. 4, lines 20-57; col.7, lines 31-35). As previously made of record, '569 teaches a biodegradable device comprising a polyhydroxyalkanoate comprising 4-hydroxybutyrate in a form of porous conduit such as NEUROTUBE™ products described by the references such as US Patent NOs. 5735863, 5584885 and 5026381. US Patent No. '569 teaches the pore size of PHA is nanometers to 500μm in diameter (i.e. as it relates to claims 1, 3-5; see co. 10, lines 31-42). '885 also teaches conduits comprising Schwann cells (i.e. neural cells), growth factors and drugs (i.e. as it relates to claim 6; see col.27-28).

In addition, as previously made of record, the issued patents US 6610764, US 6838493, US 6867247, US 7179883 and copending applications US2002/0156150 (US Application No. 10/082954) and US2002/017358 (US Application No. 10/136499) teach a biocompatible polyhydroxyalkanoate composition, or a device or a polymeric filament or fiber for a medical device comprising 4-hydroxybutyrate polymers for different medical uses including nerve regeneration. These specifications teach a biodegradable device comprising a polyhydroxyalkanoate comprising 4-hydroxybutyrate in a form of porous conduit such as NEUROTUBE™ products described by these references, which is in the form of a tube with a pore size of 5-500μm in diameter (i.e. as it relates to

as it relates to claims 1, 3-5). In addition, the intended use for nerve regeneration is not given patentable weight since the composition of the issued patents and copending applications is the same as in the instant application and can perform the same function as in the instant claimed product.

Thus, the rejections made of record are maintained.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/54593 (published Aug 2, 2001) in view of Martin et al. (2003. 16: 97-105 cited in the previous office action), for the reasons made of record in Paper No.20070202, and as follows.

Applicants argue that the prior art does not make obvious the claimed nerve conduit made of 4-hydroxybutyrate polymers in a form of a tube or sheet and having pores between 5-500um in diameter (p. 5 of the response). Applicants' arguments have been fully considered but they are not persuasive.

In response, in contrast to Applicant assertion (p.5 of the response), WO 01/54593 teaches a nerve regeneration conduit "comprising" biodegradable polymers selected from polyhydroxyalkanoate, polyhydroxybutyric acid and polyesters (i.e. as it relates to claim 1; see p. 14, claims 6-8). As previously made of record, WO01/54593 also teaches the conduit comprising Schwann cells (i.e. neural cells) or neurotrophic agents and the thickness of conduit is 5-200μm (as it relates to claims 1, 3-6; see p.2-4). Although WO01/54593 do not teach 4-hydroxybutyrate per se, Martin et al. teaches poly-4-hydroxybutyrate (P4HB) (i.e. a polymer) is polyester that belongs to the class of polyhydroxyalkanoate (PHA) (i.e. comprises 4-hydroxybutyrate) and for use in tissue regeneration (see p.97, 1st col. 1st paragraph; 2nd col. 1st paragraph). Martin et al. teach P4HB patches with a pore size of 180-240μm (as it relates to claims 4-5;see p. 100, 1st col. 2nd paragraph). Martin et al. further teach that P4HB is more stable and useful for tissue engineering. Thus, it would have been obvious to a skilled artisan to use 4-hydroxybutyrate polymers to make a nerve conduit and have expected success since 4-hydroxybutyrate polymers (P4HB) are more stable and useful for tissue engineering, such as nerve regeneration.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-6 are indefinite because Applicants recite "suitable" in the claim 1. Claims 3-6 are indefinite as depending from indefinite claim 1. The term "suitable" in claim 1 is a relative term which renders the claim indefinite. The term " suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant fails to set forth the metes and bounds of what is encompassed within the definition of "suitable". Since the metes and bounds are not unknown, a skilled artisan cannot contemplate what would be considered as suitable for nerve repair as recited in the claim. Thus the claims are indefinite.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
June 28, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER